CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number:89-081

Trade Name:Prelone

Generic Name: Prednisolone Syrup, USP, 15mg/5ml

Sponsor: Muro Pharmaceutical Inc.

Approval Date: February 4, 1986

INDICATION(s): Adrenocortical Steroid

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 89-081

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
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Approvable Letter				X
Printed Labeling	X			
Medical Review(s)				X
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)				X
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)	X			
Administrative/ Correspondence Document(s)	X			

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 89-081

APPROVAL LETTER

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 89-081

DATE APPROVAL LETTER ISSUED: FEB 4 1986

TO: Press Relations Staff (HFI-40)

FROM: ☒ Bureau of Drugs ☐ Bureau of Veterinary Medicine

ATTENTION

Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.

TYPE OF APPLICATION: ☐ ORIGINAL NDA ☐ SUPPLEMENT TO NDA ☒ ABBREVIATED ORIGINAL NDA ☐ SUPPLEMENT TO ANDA

CATEGORY: ☒ HUMAN ☐ VETERINA

TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG:
Prednisone

DOSAGE FORM: Oral Solution ORIGINAL ABBREVIATED

HOW DISPENSED: ☒ RX ☐ OTC

ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s). If amount is declared on label.)

Prednisone 15 mg/mL

NAME OF APPLICANT (Include City and State)
Muro Pharmaceuticals, Inc.
Tweksbury, MA 18976

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY
Adrenocortical Steroid

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME: Maria Shih DATE:

FORM APPROVED BY

NAME: Jack Meyer DATE:

FORM FD 1642 (2/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

ANDA 89-081

Muro Pharmaceuticals, Inc.
Attention: Joseph A. Celona
890 East Street
Tewksbury, MA 18976

FEB 4 1986

Dear Sir:

Reference is made to your abbreviated new drug application dated November 20, 1984, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Prednisolone (prednisolone) Syrup, 15 mg/5 mL.

Reference is also made to our letter of December 13, 1985.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

Any significant change in the conditions outlined in this abbreviated application requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.70 of the New Drug Regulations.

Postmarketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80 and 314.81 of the Regulations.

This Administration should be advised of any change in the marketing status of this drug.

For Initial Campaigns: We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your immediate advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Advertising and Labeling (HFN-240). Please do not use Form FD-2253 [illegible] of Advertisements and Promotional Labeling for Drugs for Human [illegible] for this initial submission.

For Subsequent Campaigns: We call your attention to Section 314.81(b)(3) of the Regulations which requires that materials for any subsequent advertising or promotional campaign, at the time of their initial use, be submitted to our Division of Drug Advertising and Labeling (HFN-240) with a completed Form FD-2253.

Sincerely yours,

Marvin Seife 2/4/86

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drugs and Biologics

BOS-DD
HFN-230
HFN-83
HFN-10
TPoux/JMeyer/MShih
R/D INITIALED BY: JMeyer/MSeife
D Utz: 2-3-86 (0271R)

JMeyer 2/4/86
MS 2/4/86
2/3/86

ANDA 89-081/S-020

Muro Pharmaceutical, Inc.
Attention: Joseph A. Celona
890 East Street
Tewksbury, MA 01876

Dear Sir:

This is in reference to your supplemental new drug application dated June 30, 1998, submitted pursuant to 21 CFR 314.70(c) "Special Supplement - Changes Being Effected" regarding your abbreviated new drug application for Prelone® (Prednisolone Syrup 15 mg/5 mL).

The supplemental application provides for information regarding the availability of two strengths being incorporated into the carton (480 mL, 240 mL & 20 mL), container (480 mL, 240 mL & 20 mL) and package insert labeling.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

1/
4-98

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research